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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,767	06/19/2001	Arthur Charles Ley	DYX-012.1 US	2306

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EXAMINER
PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
1652	11

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,767	LEY ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/6/01, 2/12/02 AND 10/28/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *8-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group I, claims 1-7 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that each of the 183 separate polypeptides in claim 13 share common features, fractionation of the claims would lead to unnecessarily repetitive examination, many of recognition sites share one or more sequence motifs such as SEQ ID NO:1 or 2, they are not unrelated sequences since they share EK-cleavable peptides and certain structural features. They further argue that Groups 190-192 "are not specific to any particular sequence, and therefore should not be restricted into three groups...SEQ ID Nos: 213, 215 and 217, specified in Claim 34 are not EK-cleavage sequences". They also argue that it would not be a serious burden upon the examiner to examine all of the groups, that there is a common classification among some of the groups and that inventions must be independent and distinct as claimed to properly restrict.

This is not found persuasive because even though each of the separate groups of claim 13 share common features, they are properly restricted because they are structurally different. The statement regarding Groups 190-192 is not fully understood. What difference does it make if SEQ ID NO: 213, 215 and 216 are not EK-cleavage sites--they are three distinct parts of claim 34 and are therefore properly restricted. The fact that there is a common classification is not probative to whether the restriction is proper, each of the groups are directed to separate things and more enters into patent examination than patent classification, e.g. commercial literature searches, 35 USC § 101 and 112 issues, etc. As to the final argument that inventions must be independent and distinct, in MPEP § 802.01 the meaning of "independent" and "distinct" is discussed, along with a discussion of the legislative history of these terms in patent law. It is concluded in MPEP § 803 that restriction

is proper when the inventions "are either independent (MPEP § 806.04 - §806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)) (emphasis added).

Finally, it is noted that examination involves examination of not only the patent and commercial literature, but also the sequences claimed. In order to examine only Group 1 the examiner must examine SEQ ID NO:1, 5-7, 210 and 211. He also must examine all of the embodiments of Xaa_1, Xaa_2, Xaa_3, Xaa_4 and Xaa_5 contained in claims 1 and 2 manually. This requirement to examine the sequences alone would mean that it would be an undue burden upon the examiner to examine all of the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

From a reading of the specification, apparently what was done was to make a phage display by placing an 86-mer onto the N-terminal end of the M13 phage gene III protein. This 86-mer contained two particular streptavidin binding sequences in particular places N-terminal to a variable 13 amino acid

region and a factor Xa cleavage site C-terminal to this 13 amino acid variable region. Approximately 2 X 10^{16} different peptides were included in the screened display. The phage were bound to streptavidin beads and the bound phage were incubated with enterokinase. Five rounds of this incubation with enterokinase were performed with increasing stringency and presumably the positive phage from the preceding round was used for the next round. Heptamers of the amino acid sequences are listed in Tables 1-4 "including the P_1' residue". (Presumably the last residue in the listed heptamer is the P_1' residue.) Apparently from this data the limitations of the instant claims were derived. Looking at only Table 4, the round 5 isolates which were presumably the most stringently detected, and only for the moment considering heptamers with Asp-Arg (D-R), as in the elected claims, and the "Xaa_4" residue, 15 of the heptamers listed (B02, B03, B06, D01, D03, D09, D12, E12, F05, G04, G05, G09, G11, H08 and H10) do not meet the requirements of claim 1 as to the "Xaa_4" position and in addition there is not an example of Thr (T) in that position. This is not even taking into account positions "Xaa_1", "Xaa_2", "Xaa_3", "Xaa_5", Z_1 and Z_2. Nor do the instant claims require that two different streptavidin binding sites be present at particular sites nor a factor Xa cleavage site, as was the case in the experimental phage displays. It is not seen how applicants arrived at the limitations of the instant claims and for the reasons outlined *supra*, it is maintained that the limitations are not be justified or enabled. Thus, one of ordinary skill in the art would not know how to make the instant invention given the disclosure in the specification. Furthermore, one of ordinary skill in the art would not believe from reading the instant specification that the inventors had the claimed invention in their possession at the time the application was filed.

The examiner has made a concerted effort to understand the claimed invention and if he has construed the specification wrong applicants should specifically point this out.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Denhez, et al. (U), Escriva, et al. (V), Dear, et al. (W), Hollander, et al. (X), Kerfield, et al. (U-2) or Morris, et al. (V-2). Denhez, et al. teach the instant recognition sequence from amino acids 655-659 of Fig. 2; Escriva, et al. in Fig. 1, the sequence for Artemia FTZ-F1 in the FTZ-F1 (subfamily V); Dear, et al. in *Drosophila* in Group 3 of Fig. 5B; Hollander, et al. in Fig. 3; Kerfield, et al. in *C. purpuraum* B830α1 of Table 1; and Morris, et al. in the first protein listed in Fig. 1. It is maintained that any protein meets the requirements of a "protein of interest" as defined in the paragraph spanning pages 17-18.

Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either of Denhez, et al. (U), Escriva, et al. (V), Dear, et al. (W), Hollander, et al. (X), Kerfield, et al. (U-2) or Morris, et al. (V-2).

The instant references are characterized *supra*. The examiner cannot tell if some ligand recognition sequence or some streptavidin binding domain is present at position Z_1, but if not it would have been obvious to place one there so as to bind the sequence to a substratum for ease of study and/or analysis of the recognition sequence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 9, 2003